K133260

JUN 27 2014

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

1. **Type of 510(k):**
   Traditional 510(k)

2. **Prepared Date:**
   May 2, 2014

3. **Submission Sponsor:**
   Tianjin Empecs Medical Device Co., Ltd.

4. **Address:**
   No.35 and 37, Yingcheng street, Hangu, Binhai New Area, Tianjin, 300480 China

5. **Contact:**
   Eric.Chae, Regulatory Affairs Manager
   Phone: +82-70-7124-0474
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6. **Registration Number:**
   9616530

7. **Measurement:**
   Whole blood glucose

8. **Type of Test:**
   Quantitative, utilizing Glucose Oxidase technology

9. **Device Name:**
   Medisign MM3000 Blood Glucose Monitoring System
   Medisign MM3000 Multi Blood Glucose Monitoring System

10. Common Classification Name:

Blood Glucose Test System

11. Classification:

Product Code	Classification	Regulation Section	Panel
NBW - System, Test, Blood Glucose, Over The Counter	Class II	21 CFR 862.1345	75-Chemistry
CGA - Glucose Oxidase, Glucose	Class II	21 CFR 862.1345	75-Chemistry
JJX - Quality Control Material	Class I	21 CFR 862.1660	75-Chemistry
JQP - Calculator/data processing module for clinical use.	Class I	21 CFR 862.2100	75-Chemistry

12. Predicate Device Information:

Device Name: Medisign MM1100 Blood Glucose Monitoring System, Medisign MM1100 Multi Blood Glucose Monitoring System

510(k) Number: K111456

13. Intended Use

Medisign® MM3000 Blood Glucose Monitoring System

The Medisign® MM3000 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The Medisign® MM3000 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The Medisign® MM3000 meter contains some speaking functions but is not intended for use by the visually impaired.

The Medisign® MM3000 Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Medisign® MM3000 Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Medisign® MM3000Test Strips are for use with the Medisign® MM3000 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the

fingertips, forearm or palm.

The Medisign® Glucose Control Solutions are intended for use with the Medisign® MM3000 meter and Medisign® MM3000 Test Strips as a quality control check to verify the meter and test strip are working together properly, and that the test is performing correctly.

The Medisign Link Diabetes Management Software is personal computer(PC) based software intended for use in home and professional settings to help people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results for effective controlling and managing blood glucose.

Medisign® MM3000 Multi Blood Glucose Monitoring System

The Medisign® MM3000 Multi Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) fresh capillary whole blood from fingertip, palm, or forearm. The Medisign® MM3000 Multi Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with single-use, auto-disabling lancing devices. The Medisign® MM3000 Multi meter contains some speaking functions but is not intended for use by the visually impaired.

The Medisign® MM3000 Multi Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Medisign® MM3000 Multi Blood Glucose Test Strips are for use with the Medisign® MM3000 Multi Blood Glucose Meter to quantitatively measure glucose (sugar) fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

The Medisign® MM3000 Glucose Control Solutions are intended for use with the Medisign® MM3000 meter and Medisign® MM3000 Test Strips as a quality control check to verify the meter and test strip are working together properly, and that the test is performing correctly.

The Medisign Link Diabetes Management Software is personal computer(PC) based software intended for use in home and professional settings to help people with diabetes and their

healthcare professionals in the review, analysis and evaluation of glucose test results for effective controlling and managing blood glucose.

14. Device Description

Medisign Blood Glucose Monitoring System measures the glucose in the whole blood sample by using a small electrical current produced by chemical reaction between glucose in the blood and glucose oxidase (GOD) on the test strip. This current is proportionally converted to the amount of glucose in the blood sample to display as the blood glucose result. Glucose measurements are reported as plasma equivalents. Blood glucose results from test strips that are plasma-equivalent are approximately 11% higher than those obtained with whole-blood referenced test strips.

Medisign MM3000 Blood Glucose Monitoring System is basically provided with a blood glucose meter, blood glucose test strips, a lancing device, sterile lancets, and a carrying bag including user manual, quick reference manual and log book. Some kits do not include blood glucose test strips. Blood glucose test strips, blood glucose control solutions (1, 2, 3 levels), diabetes management software, and data transporting cable are sold separately.

Medisign MM3000 Multi Blood Glucose Monitoring System is basically provided with a blood glucose meter, blood glucose test strips, and a carrying bag including user manual, quick reference manual and log book. Some kits do not include blood glucose test strips. Disposable lancing device, blood glucose test strips, blood glucose control solutions (1,2,3 levels), diabetes management software, and data transporting cable are sold separately.

Each box of test strips contains one vial of 10 test strips, one vial of 25 test strips, one vial of 50 test strips, or two vials of 25 test strips. Also, each box may contain 25 test strips packed with single aluminum foiled pack or 50 test strips packed with single aluminum foiled pack. Each test strip contains the following reagent compositions: glucose oxidase (A. Niger) –2.5 units, redox mediator – 32.3μg and buffer & non-reactant – 50.5μg.

Each box of control solutions (1, 2, 3 levels) contains one vial of aqueous control solution (4ml each): Level 1 contains 0.03% concentrations of glucose (approximately 40 mg/dL) and Level 2 contains 0.11% concentrations of glucose (approximately 85 mg/dL) and Level 3 contains 0.23% concentrations of glucose (approximately 260 mg/dL).

15. Device Modifications

The modified Medisign MM3000Blood Glucose Monitoring System and Medisign MM3000 Multi Blood Glucose Monitoring System have the following that are identically same as the predicate device:

- ☐ Intended use
- ☐ Operation principle
- ☐ Fundamental scientific technology
- ☐ Raw materials
- ☐ Operation environment
- ☐ Measuring range

The modifications from the predicate device are as follows:

- ☐ Meter shape
- ☐ Type of a battery
- ☐ Change to the memory capacity
- Change to the expiration date of the test strip
- Change to assigned Glucose Control Solutions level title(from A,B to 2,3)
- Addition of an Glucose Control Solution low level (level title: Level 1)
- ☐ Addition of an alarm function
- ☐ Addition of the hypoglycemic indicator
- ☐ Addition of average results for 7,28 days
- ☐ Addition of a lancing device to the meter set for single user
- ☐ Addition of a voice function feature
- Addition of a single test strip package
- ☐ Exclude a check strip as the optional components (Control Solutions are enough to cover the check strip function of the control test)

16. Comparison to the Predicate Device

Similarities			
Features	**Predicate Device (K111456)**	**Candidate Device**	**SE Decision**
Intended Use	Refer to the Intended Use Section	Same	SE
Enzyme	Glucose Oxidase (*Aspergillus Niger*)	Same	SE

Test Principle	Electrochemical reaction	Same	SE
Test Sample	Capillary whole blood	Same	SE
Electrode Material	Carbon	Same	SE
Coding of Test Strip	Auto coding	Same	SE
Calibration	Plasma equivalent	Same	SE
Operating Temperature	50 – 104°F	Same	SE
Operating Humidity	10 – 90%RH	Same	SE
Hematocrit Range	30 – 55%	Same	SE
Alternate Site Testing Site	Palm, Forearm	Same	SE
Measuring Time	5 seconds	Same	SE
Sample Volume	Minimum 0.5 micro liter	Same	SE
Measuring Range	20 - 600 mg/dL	Same	SE
Pre/Post-meal flagging	Yes	Same	SE
Battery Life	Approximately more than 1,000 tests	Same	SE
Test Strip Ejector	Available	Same	SE
Differences			
Battery	Two(2) 3.0V Lithium batteries(CR2032)	Two(2) 1.5V Alkaline batteries(LR03, AAA)	-
Memory Capacity	300 results with date, time and flag	500 results with date, time and flag	-
Test Strip Expiration Date	18 months (3 months after first opening)	24 months (3 months after first opening)	-
Glucose Control Solution Level Title	Level A Level B	Level 1 Level 2 Level 3	
Alarm Function	N/A	Three(3) different interval settings available	-
Hypoglycemic indicator	N/A	Available	-
Averaging Results	14 days	7,14 and 28 days	-

Lancing Device for single user	N/A	Included to the single user system(for Over the count use only)	-
Voice Function	N/A	Available	-
Test Strip Packaging	Desiccant vial	▪ Desiccant vial or ▪ Waterproof aluminum foil pack for single test strip packing	-
Check Strip	Optional Component	N/A	-

17. Performance Evaluation of Modified Device

The modified device has the same intended use, fundamental scientific technology and performance characteristics as the predicate device. Therefore, the performance, safety and effectiveness have not been changed from the predicate device. However, to confirm these changes have not brought any unexpected functional failure or adverse effect, a system performance test including human factor study was conducted. The test procedures were all the same as those applied to the predicate device submission. As a result, all tests have been proved satisfactory according to the predetermined acceptance criteria. Refer to section #13 for the procedures and results.

18. Summary of Design Control Activities

13.1 Risk analysis

The Risk assessment was conducted and The risk analysis method used to assess the impact of the modification was a Failure Modes and Effects Analysis(FMEA). Detected risks were assessed and controlled as low as possible.

13.2 Disinfection Study

Disinfectant CaviWipes® with the EPA registration number of 46781-8 has been validated demonstrating complete inactivation of the live virus inoculated on the materials of the meter and the reusable lancing device. The result showed that the disinfectant in preventing the spread of blood born pathogens, particularly hepatitis B virus(HBV).

A robustness performance test for a reusable lancing device also demonstrated that with 200 pre-cleanings and 200 disinfection cycles, which is equivalent to 1 times use per a week for 3 years for the lay user at home. As a result, there was no deterioration on the performance or external materials of the lancing device.

A robustness performance test for the meter demonstrated that with 1,100 pre-cleanings and 1,100 disinfection cycles, which is equivalent to 10 times use per day for 3 years in a professional

setting. The number of the cycle also includes those for the lay user at home. As a result, there was no deterioration on the performance or external materials of the meter.

13.3 Verification Activities for Modified Features

Verification activities were successfully executed to validate the modification and all test results fell within the acceptance criteria.(see attachment section #24)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

TIANJIN EMPECS MEDICAL DEVICE CO., LTD.
C/O PRISCILLA CHUNG
2651 E CHAPMAN AVE STE 100
FULLERTON CA 92831

June 27, 2014

Re: K133260
Trade/Device Name: Medisign MM3000 Blood Glucose Monitoring System,
Medisign MM3000 Multi Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX, JQP
Dated: May 20, 2014
Received: May 20, 2014

Dear Ms. Priscilla Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k133260

Device Name
Medisign MM3000 Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Medisign® MM3000 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The Medisign® MM3000 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The Medisign® MM3000 meter contains some speaking functions but is not intended for use by the visually impaired.

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Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Stayce Beck
-S FDA

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k133260

Device Name
Medisign MM3000 Multi Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Medisign® MM3000 Multi Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) fresh capillary whole blood from fingertip, palm, or forearm. The Medisign® MM3000 Multi Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single-use, auto-disabling lancing devices. The Medisign® MM3000 Multi meter contains some speaking functions but is not intended for use by the visually impaired.

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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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